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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,866	09/28/2006	Masanobu Kobayashi	18220-003USIONR-A0403P-US	3917
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EXAMINER NATARAJAN, MEERA				
ART UNIT 1643		PAPER NUMBER		
NOTIFICATION DATE 09/30/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/551,866

Applicant(s)

KOBAYASHI ET AL.

Examiner

MEERA NATARAJAN

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10, 17, 41-43 and 45-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 17, 41-43 and 45-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendments in the reply filed on 06/24/2008 is acknowledged and entered in to the record.
2. Accordingly, Claims 2-9, 11-16, 18-40, and 44 have been cancelled.
3. Claims 1, 10, 17, 41-43, 45-53 are pending and will be examined on the merits.

Claim Rejections Maintained - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection Claims 1, 10, 17 and new claims 41-43, 45-50 under 35 U.S.C. 102(b) as being anticipated by Wang et al. (Archives of Biochemistry and Biophysics, Vol. 390, pp9-18, 2001) are maintained for the reasons of record..
6. Applicant's argue that Wang et al. does not disclose methods for screening for a therapeutic agent for cancer, for an apoptosis-inducing agent, an anticancer agent potentiator, or substances that enhance or inhibit the activity of Pim-1. Applicant's argue that Wang et al. only discloses that there is a correlation between PMA and U937 cell differentiation, but does not disclose, or even, suggest a correlation between PMA and the phosphorylation activity of Pim-1. Applicant's also argue Wang et al. does not disclose using an antibody as required by claims 43, 46, 48, and 50. These arguments have been carefully considered but are not found persuasive.

7. As stated in the office action mailed 02/25/2008, Wang et al. clearly perform the active method steps recited in the claims: (a) contacting a test substance with Pim-1 or a partial peptide thereof or a salt thereof, (b) detect the phosphorylation activity of Pim-1, and (c) identify a substance that enhances or inhibits the activity of Pim-1. Wang et al. perform the active method steps in the assays depicted in Fig. 5. Wang et al. contacts Pim-1 expressing cells with a test substance, PMA, and then detects kinase activity, enzymatic activity, and total protein. The active steps (a)-(c) were performed by Wang et al. and therefore inherently perform methods of screening for a therapeutic agent for cancer, for an apoptosis-inducing agent, an anticancer agent potentiator, or substances that enhance or inhibit the activity of Pim-1. Even if a negative result was obtained, and the test substance, PMA, did not induce apoptosis, the active method steps were still performed and therefore read on the claimed invention. An anti-Pim1 antibody was used to detect total amount of Pim-1 protein and to immunoprecipitate Pim-1. Although the amount of phosphorylated Pim-1 is not shown, the Pim-1 antibody would "recognize" phosphorylated Pim-1. In addition wild-type Pim-1-GFP was assessed in the presence of PMA and therefore reads on the limitation of detecting activity by determining expression level of a reporter gene. The assay was compared to kinase dead Pim-1 suggesting that increased GFP expression was due to kinase activity (i.e. phosphorylation).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1, 10, 17 and new claims 41-43, 45-53 are rejected under 35 U.S.C.

103(a) as being unpatentable over Wang et al. (Archives of Biochemistry and

Biophysics, Vol. 390, pp9-18, 2001A) in view of Wang et al. (J. Vet. Sci, Vol. 2(3), pp.167-179, 2001B).

11. The Claims are drawn to methods for screening for a therapeutic agent for cancer, for an apoptosis-inducing agent, an anticancer agent potentiator, or substances that enhance or inhibit the activity of Pim-1, comprising the active steps (a) contacting a test substance with Pim-1 or a partial peptide thereof or a salt thereof, (b) detect the phosphorylation activity of Pim-1, and (c) identify a substance that enhances or inhibits the activity of Pim-1, wherein the agents are for pancreatic cancer.

12. The teachings of Wang et al. 2001A are presented in the 102(b) rejection set forth above. Wang et al. does not teach a role of Pim-1 and pancreatic cancer.

13. Wang et al. 2001B teach that Pim-1 kinases are highly conserved through evolution in multicellular organisms and are involved in the control of cell growth,

differentiation, and apoptosis and play a role in cell survival, proliferation and tumorigenesis.

14. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the methods of identifying agents as taught by Wang et al. 2001A for therapeutic purposes for cancer, including pancreatic cancer. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Wang et al. 2001B that Pim-1 plays a role in several process that are involved with cancer progression.

All other objections/rejections are withdrawn in view of applicant's amendments filed on 06/24/2008.

Conclusion

15. Claims 1, 10, 17, 41-43, 45-53 are rejected.
16. No Claim is allowed.
17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643